GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:344
ANSWERED ON:13.12.2000
MARKETING OF DRUGS
KANTI SINGH;RAGHUVANSH PRASAD SINGH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware that various drugs and formulations banned in USA and other foreign countries are still being marketed in the country;

(b) if so, the details thereof;

(c) whether the Government have examined this issue in consultation with various laboratories and other experts of the All India Institute of Medical Sciences; and

(d) if so, the details of such banned drugs allowed to be marketed in the country?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) to (d): A statement is laid on the Table of the Lok Sabha.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 344 FOR 13.12.2000

Certain drugs and formulations banned in some countries at times continue to be marketed in other countries because the decision to do so is normally based on risk assessment process which is influenced by a number of factors such as the disease pattern in a country, the varying reactions of certain ethnic groups in a given population to the drug and the availability of safer substitutes as well as the cost factor involved in the treatment of a particular disease. There is also the overall awareness that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

The risk assessment of an approved drug begins with information about its review, restriction, discontinuation or ban in any country. The evaluation of the data is done in consultation with leading experts in the given specialisation. Based on their advice, the matter is placed before the Drug Technical Advisory Board (DTAB), a statutory body which comprises of representatives from the medical profession, the State drug enforcement authorities, experts institutions/agencies that advise Government on technical issues related to the implementation of the Drugs and Cosmetics Act 1940, like whether or not to ban/phase out an existing drug.

Out of 46 drugs previously reported by the WHO as banned in some countries, 26 drugs were never marketed in this country. Of the remaining 20 drugs, 13 drugs have been discontinued based on expert evaluation and recommendation of the DTAB. While 7 drugs have been allowed to be continued to be marketed subject to cautionary statement and contra- indications being given on the label and in some cases on the package insert. Details of the 46 drugs mentioned by WHO and their status in the country are Annexed.

Recently 2 more drugs viz. Cisapride and Phenypropanolamine have been withdrawn in USA in July,2000 and November, 2000 respectively. The need for their use in the country or otherwise is currently under evaluation in consultation with experts.

ANNEXURE

PRODUCTS RECOMMENDED FOR WITHDRAWAL IN SOME COUNTRIES AS

REPORTED BY WHO

Sl.No	Name of the drug	Status in the country
1.	Nialamide	Banned
2.	Practolol	Banned
3.	Sodium Borate	Banned

4.	Dugynon Socrodyl	Banned
5.	Nitrofuran	Sale with restriction
6.	Amidopyrinc	Banned
7	Phenformin	Sale with restriction
8.	Hologenated Hydroxyquinolinc	Sale with restriction
9.	Oxyphcnisatin	Never allowed for marketing
10.	Phenacatin	Banned
11.	Ethylien Dichleride	Never allowed for marketing
12.	Triazolam	Never allowed for arketing
13.	Methapyrilene	Banned
14.	Alclofenac	Never allowed for marketing
15.	Chlormadinone Acetate	Never allowed for marketing
16.	Lynestrenol	Sale with restriction
17.	Tetacycline	Banned (Liquid Oral Preparation)
18.	Aristolichic Acid	Never allowed for marketing
19.	Tionilic Acid	Never allowed for marketing
20.	Benexaprofen	Never allowed for marketing
21.	Zimeldine	Never allowed for marketing
22.	Indoprofen	Never allowed for marketing
23.	Piperazine	Sale with restriction
24.	Phenylbutazone/ Oxyphenbutazone	Sale with restriction
25.	Feprazone	Never allowed for marketing
26.	Fenclofenac	Never allowed for marketing
27.	Analgin (Dipyrone)	Sale with restriction
28.	Methaqualone	Banned
29.	Propanidid	Banned
30.	Nitrofazole	Never allowed for marketing
31.	Zomepirac	Never allowed for marketing
32.	Prasteronc	Never allowed for marketing
33.	Molsidamine	Never allowed for marketing
34.	Nomifensinc	Never allowed for marketing
35.	Fencamfamin	Never allowed for marketing
36.	Methandienone	Banned
37.	Suprofen	Never allowed for marketing
38.	Dantrabine Sodium	Never allowed for marketing
39.	Potassium Canrenoate	Never allowed for marketing
40.	Bromiseval (Hyprotic)	Never allowed for marketing
41.	Isozicam	Never allowed for marketing
42.	Cianidanal	Never allowed for marketing
43.	Indalpine	Never allowed for marketing
44.	Suloctidil	Never allowed for marketing
45.	Fenfluramine	Banned
46.	Dexfenfluramine	Banned